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Remarks

This Amendment and Response is in reply to the Office Action mailed April 10, 2006 in the subject application.

Claims 1-16 are pending. Claims 12-14 and 16 have been cancelled. Claims 1, 6, 7 and 15 have been amended, as shown above and discussed in greater detail below.

Claim Objections

In the Office Action, claims 6, 14 and 15 were objected to for several informalities. All of the asserted informalities have been corrected in the amendments proposed above.

The objections should now be withdrawn.

Rejection under 35 U.S.C. 101

In the Office Action, claims 12-14 and 16 were rejected as being directed to non-statutory subject matter and lacking utility.

Applicants disagree with this rejection. However, as indicated above, claims 12-14 and 16 have been cancelled, obviating this rejection.

The rejection of these claims should now be withdrawn.

Rejections under 35 USC 112, paragraph 2

Claims 1-16 have been rejected in the Office Action for indefiniteness for failure to particularly point out and distinctly claim the subject matter Applicants consider to be their invention.

As indicated above, several of these claims have been amended along the lines suggested by the examiner, though Applicants disagree that the claims as originally presented were indefinite. Other clarifying amendments were made. Also, claims 12-14 and 16 have been cancelled. No new subject matter was introduced by any of these amendments.

With respect to the further comments concerning claims 5 and 9-11, Applicants submit the following.

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The Office Action states on page 8 with respect to claims 5 and 9-11 that

"the limitation bPTH/80" makes the claims vague and indefinite because it is unclear whether the limitation is intended to mean the initial dose of vitamin D equals the amount of bPTH divided by a factor of 80; the initial dose equals the amount of some other PTH (called PTH/80); the initial dose equals a dose (or an initial dose) of the dose of Vitamin D for the hormone bPTH/80; etc. The examiner maintains that the limitation renders claims 5 and 9-11 indefinite and the rejection is maintained."

Applicants completely disagree that the claim language as presented is indefinite such that which the inventors consider to be their invention is not pointed out distinctly and with particularity. The numerous variations of allegedly possible interpretations included in the examiner's statement above are simply not supported by the claim language itself particularly read in light of the specification as originally filed. The limitation of "bPTH/80" as stated in these claims clearly means baseline PTH (i.e., bPTH) divided by a factor of 80. As clearly stated at page 4, the beginning of the Detailed Description, of the specification (emphasis added):

"The term "initial dose" shall refer to the dose in micrograms that is the first or starting dose of the vitamin D compound administered to the patient as the patient commences treatment for secondary hyperparathyroidism and/or renal osteodystrophy. *Initial dose is equal to the baseline PTH divided by a denominator based upon the outcome of a regression model.*"

In addition, at page 5 of the subject application, it states:

"We have determined that the initial dosing of vitamin D compounds can be based on patient baseline PTH while maintaining a safely profile consistent with approved dosing protocols, with no difference in the incidence of hypercalcemia. The method of the present invention uses regression analysis, preferably a zero-intercept linear model, to calculate an initial dose for the vitamin D compound."

At page 6, the specification states:

"The determination of the initial dose is accomplished as follows. As a first step, the patient's baseline PTH value is determined prior to commencement of treatment with the vitamin D compound. Generally, patients having PTH values greater than 200 picograms per milliliter are considered to be candidates for vitamin D therapy. The

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determination of PTH values, including baseline PTH values is accomplished using methods that are well known in the art."

Withdrawal of this rejection is respectfully requested.

Prior Art Rejections

Claims 10 and 11 stand rejected as anticipated by Martin. The Office Action states that Martin discloses treating ESRD patients and secondary hyperparathyroidism by administering an initial dose of a vitamin D. The Office Action further states "Martin discloses a baseline PHT (*sic*) and a baseline PTH 800 pg/ml which is divisible by 80. Thus, Martin anticipates claims 10 and 11."

Applicants strongly disagree with this conclusion.

A careful reading clearly reveals that Martin does not disclose that the **initial dose of vitamin D** administered to the ESRD patients was "about the patient baseline PTH/80", as set forth in claims 10 and 11. Rather, Figure 1 clearly shows that the **initial dose of vitamin D was 0.04 micrograms per kilogram of patient weight**. As such, Martin cannot anticipate Applicants' invention as set forth in claims 10 and 11 and the rejection should be withdrawn.

Claims 10 and 11 also stand rejected as anticipated by Knutson (U.S. 5602116). The Office Action reasons Knutson discloses treating ESRD patients by administering an initial dose of vitamin D, a baseline PTH of 480, which is divisible by 80 and therefore allegedly anticipates claims 10 and 11.

Applicants again must strongly disagree with this analysis and conclusion as impermissibly ignoring and failing to grasp the explicit and particularized relationship between the initial dose of vitamin D administered and the patient's baseline PTH level, as set forth clearly in these rejected claims. As amended, these claims state, with emphasis added:

10. A method of treating a patient for end stage renal disease using a vitamin D therapy, comprising administering an initial dose of vitamin D to the patient *wherein the initial dose of vitamin D is about patient baseline parathyroid hormone/80 (bPTH/80) and bPTH is the baseline PTH for the patient.*

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11. A method of treating a patient for secondary hyperparathyroidism using a vitamin D therapy, comprising administering an initial dose of vitamin D to the patient *wherein the initial dose of vitamin D is about patient baseline parathyroid hormone/80 (bPTH/80) and bPTH is the baseline PTH for the patient.*

Thus, in view of the recited relationship between the initial dose of vitamin D, any reference that fails to disclose this recited relationship simply cannot anticipate. With respect to Knutson in particular, the examiner's attention is drawn to col. 3, lines 9-11 and lines 17-19, which discuss the minimum effective dose for preventing secondary hyperparathyroidism is an amount per day (e.g., in the range of 0.25 to 0.50 mcg/day), and lines 64-66 which discuss dosing in an amount per week; and col. 6, lines 59-63, which discuss preferred oral administration by unit dosage form of about 0.25 to about 5.0 micrograms in a pharmaceutically acceptable carrier. Applicants especially note that even Example 3 itself, pointed to by the examiner, discloses that the patients' initial dose after 8 weeks of washout was 4 micrograms/day for 6 weeks. Knutson does not disclose (or suggest) the relationship between initial dose of vitamin D and the patient's baseline PTH.

At best, Knutson merely acknowledges the complexity of dosing:

"...The specific doses for each particular patient depends of a wide variety of factors, for example, on the efficacy of a specific compound employed, on the age, body weight, general state of health, sex, on the diet, on the timing and mode of administration, on the rate of excretion, and on medicaments used in combination and the severity of the particular disorder to which the therapy is applied." Col. 6. line 66-col. 7, line 13 (emphasis added).

No specific guidance is provided by Knutson on a particular relationship between initial dose and any single factor or group of factors associated with a particular patient. Knutson is ~~un~~insufficient for at least these reasons to anticipate applicants' claimed invention and the rejection should be withdrawn.

Claims 1-16 stand rejected as obvious over Martin in view of Riviere (U.S. 6066091) and SAS Technical Support GRAPH/GPLOT 1990.

As indicated above, claims 12-14 and 16 have been cancelled, therefore Applicants' remarks on obviousness relate to the remaining claims 1-11 and 15.

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Applicants disagree with the analysis and conclusion of obviousness based on the stated analysis. As pointed out above, Martin fails to teach or suggest that "the initial dose of a vitamin D is about the patient's baseline PTH/80", as set forth in each of the independent claims remaining in the subject application.

Rather, Martin teaches only that the initial dose is based on patient body weight. As shown in Figure 1 of Martin, initial dose of a vitamin D is calculated from the formula 0.04 micrograms/kilogram patient body weight. Neither Riviere nor SAS Technical Support GRAPH/GPLOT (discussed in detail in Applicants' prior response) compensates for the deficiencies of Martin.

Applicants further submit that the proposed combination is improper since both Riviere and SAS paper use nonlinear terms that were derived considerably differently than the linear regression methods used by the inventor to determine initial dose in the present method. Therefore, one of ordinary skill in the art would have understood that it therefore does not make sense to combine the cited references as suggested by the examiner. Doing so does not achieve Applicants' invention as claimed.

Thus, the rejection is improper and should be withdrawn.

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Conclusion

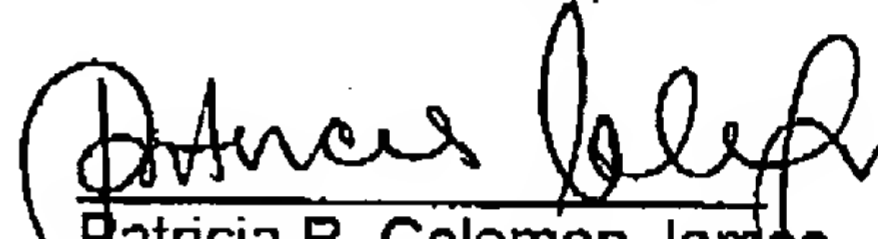
Applicants respectfully submit that the subject application is in condition for allowance and prompt allowance thereof is respectfully requested.

The examiner is urged to telephone the undersigned at 847 937-4558 to facilitate resolution of any remaining issues so that the subject application can be processed for allowance promptly.

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